K071665

ScoutPro Slitter Tool Advanced

Special 510(k) Premarket Notification

JUL 18 2007

1. 510(k) SUMMARY

Name and Address of Sponsor:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number: 1028232

Device Name:

Proprietary Name:	ScoutPro Slitter Tool Advanced
Classification:	Class II (21 CFR 870.1250; 870.1310; 870.1330)
Classification Name:	Wire, Guide, Catheters, Percutaneous
Product Code:	DQY, DRE, DQX

General Description:

The ScoutPro family of introducer systems and accessories is specifically used for the placement of coronary sinus leads. It is designed to assist with introducing leads into the vessels of the left side of the heart via the coronary sinus. The system also facilitates access to the coronary sinus venous system as well as probing the coronary sinus. The following ScoutPro accessory is subject to this Special 510 (k):

- **ScoutPro Slitter Tool Advanced**

Device Modifications:

The ScoutPro Slitter Tool Advanced represents further development of the ScoutPro Slitter Tool, which is part of the ScoutPro family of coronary sinus lead delivery systems. The main difference between the modified Slitter Tool Advanced and its predecessor is a more ergonomic design of the grip in order to optimize the handling and to enable a smooth removal of the delivery system. The optimized design is achieved by fabricating the entire device out of stainless steel. The Slitter Tool Advanced can be used with all BIOTRONIK coronary sinus leads with diameters 4.1F to 7.2F. Thus the optimized Slitter Tool Advanced covers the same lead diameter range as the two preceding Slitter Tools combined. The usage of the Slitter Tool remains unchanged and the product characteristics such as indications, contraindications, and function of the Slitter Tool Advanced are identical to the previous Slitter Tool.

The ScoutPro Slitter Tool Advanced is a separately sold accessory that can be used in conjunction with the ScoutPro family of coronary sinus lead introducer systems.

Predicate Devices:

BIOTRONIK proposes the following delivery system cleared through 510(k) notification as the predicate device for the ScoutPro Slitter Tool Advanced described in this Special 510(k):

- BIOTRONIK's ScoutPro 7F (#K060807, 04-24-2006)

Indication for Use:

The ScoutPro Slitter Tool Advanced is used in conjunction with the ScoutPro CS Lead Introducer System to facilitate lead implantation in the left of the heart via the coronary sinus.

Name and Address of Manufacturer:	BIOTRONIK GmbH & Co. KG Woermannkehre 1, 12359 Berlin, Germany 011-49-30-689-05-1210
Manufacturer's Registration Number:	9610139
Name and Address of Contract Manufacturer:	BIOTRONIK AG Ackerstraße 6 8180 Bülach, Switzerland 011-41-44-864-5169
Contract Manufacturer's Registration Number:	8043892
Contact Person(s) and Phone Number:	Jon Brumbaugh Vice President, Regulatory Affairs and Compliance Phone (888) 345-0374 Fax (503) 635-9936 jon.brumbaugh@biotronik.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2007

Biotronik, Inc.
c/o Mr. Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, OR 97035

Re: K071665
ScoutPro Slitter Tool Advanced
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: June 15, 2007
Received: June 18, 2007

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: ScoutPro Slitter Tool Advanced

Indications for Use:

The ScoutPro Slitter Tool Advanced is used in conjunction with the ScoutPro CS Lead Introducer System to facilitate lead implantation in the left of the heart via the coronary sinus.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K074665